

IV. 510(K) SUMMARY: CARESIDE™ HDL-CHOLESTEROL SAFETY AND EFFECTIVENESS

I. Applicant Information

A. Applicant Name	Exigent Diagnostics, Inc.
B. Applicant/Manufacturer Address	6100 Bristol Parkway Culver City, CA 90230
C. Telephone Number	310-338-6767
D. Contact Person	Kenneth B. Asarch, Pharm.D., Ph.D.
E. FAX Number	310-338-6789
F. e-Mail Address	asarchk@worldnet.att.net
G. Date 510(k) Summary prepared	May 29, 1998

II. Device Information

A. Device Name (Trade)	CARESIDE™ HDL-Cholesterol
B. Device Name (Classification)	HDL-Cholesterol test system
C. Device Classification	Clinical chemistry panel HDL-Cholesterol test system Regulation Number: 21 CFR 862.1475 Regulatory Class I Classification Number: 75LBS
D. Special controls and performance standards	None applicable

III. Substantial Equivalence Claim

A. General equivalency claim

The ability to monitor analyte-specific biochemical reactions in dry film and other formats is widely recognized and has gained widespread acceptance for use in chemistry assays.

HDL-Cholesterol *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including HDL-cholesterol products which utilize enzymatic (cholesterol oxidase) generation of hydrogen peroxide from free and liberated cholesterol which reacts with chromogens in a peroxidase catalyzed reaction to form a dye.

B. Specific equivalency claim

This CARESIDE™ HDL-Cholesterol test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of HDL-cholesterol on the Vitros DT 60 II.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) Vitros HDLC Slides for Johnson and Johnson's Vitros DT 60 (formerly Eastman Kodak's DT 60 II).
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Predicate Device 510K number:	K912844/A
Product Code:	75LBS

IV. Device Description

CARESIDE™ HDL-Cholesterol cartridges are used with the Exigent Diagnostics CARESIDE™ Analyzer to measure HDL-cholesterol concentration in pre-treated serum or plasma specimens. The CARESIDE™ HDL-Cholesterol cartridge, a single use disposable *in vitro* diagnostic test cartridge, delivers a measured volume of pre-treated serum or plasma to a dry film to initiate the measurement of HDL-cholesterol concentration. The film cartridge (patent pending) contains all reagents necessary to measure HDL-cholesterol concentration.

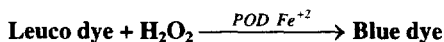
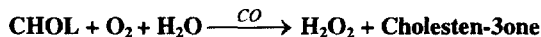
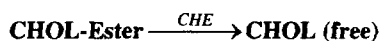
A. Explanation of Device Function

Each Exigent Diagnostics CARESIDE™ HDL-Cholesterol cartridge consists of a HDL-cholesterol-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the pre-treated specimen into the cartridge sample deposition well, closes the lid and inserts the cartridge into the Exigent Diagnostics CARESIDE™ Analyzer.

Once loaded, the CARESIDE™ analyzer scans the cartridge barcode, brings the cartridge and the contained specimen to 37°C, and spins the cartridge to move the sample from the sample deposition well into the cartridge channels and chambers. Ten microliters of sample remains in the metering passage. Any excess sample flows into an overflow well.

The ten microliters of pre-treated sample is automatically dispensed onto the multi-layer reagent film. The spreading layer distributes the sample evenly on the film, and the sample moves through a reflection layer into the detection layer. Cholesterol is dissociated from protein by the action of lipoprotein lipase (LPL) and a surfactant. Cholesterol esterase (CHE) hydrolyzes the cholesterol esters (CHOL-ester) to liberated cholesterol. Endogenous cholesterol and the liberated cholesterol react with oxygen and water to produce hydrogen peroxide in a cholesterol oxidase (CO) catalyzed reaction. Peroxidase (POD) then catalyzes the reaction of the hydrogen peroxide with a diarylimidazole leuco dye to produce a blue chromogen. The color intensity of the resulting blue dye, as measured by the amount of reflected light at 615 nanometers directly relates to the HDL-cholesterol concentration of the specimen.

Test Reaction Sequence:



As the cartridges spin, a photodiode measures reflectance of light emitted by a wavelength-specific light emitting diode (LED) at a fixed time. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate HDL-cholesterol concentration.

B. Test Summary

HDL-Cholesterol in blood comprises all of the cholesterol found in various lipoproteins. Cholesterol is the major component of the low-density lipoprotein fraction, and a minor component of the very low-density lipoprotein and high-density lipoprotein fractions. Cholesterol measurements are used in classifying patients according to risk of coronary heart disease, in the diagnosis and treatment of various primary or secondary hyperlipidemias, and to monitor changes in cholesterol levels resulting from treatment. Elevated LDLC has consistently been associated with incidence of atherosclerosis. There is also a strong correlation between considerably elevated cholesterol levels and an increased tendency for atherosclerosis. However, HDL- cholesterol concentration and cardiovascular disease risk are inversely related. Measurement of total and HDL-cholesterol in serum is useful in evaluating cardiovascular disease risk.

V. **Intended Use**

A. Intended Use

The CARESIDE™ HDL-Cholesterol cartridge is intended for *in vitro* diagnostic use in conjunction with the Exigent Diagnostics CARESIDE™ Analyzer to quantitatively measure HDL-cholesterol concentration in pre-treated serum or plasma.

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with disorders of lipid and lipoprotein metabolism.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ HDL-Cholesterol	Vitros HDLC DT Slides
Intended Use	Primarily to aid in the diagnosis and treatment of patients with disorders of lipid and lipoprotein metabolism.	Same
Indications	For <i>in vitro</i> diagnostic use. For professional laboratory.	For <i>in vitro</i> diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film based already on the U.S. market, including HDL-cholesterol products which utilize cholesterol esterase sample treatment followed by cholesterol oxidase generation of hydrogen peroxide from free and liberated cholesterol which reacts with a leuco dye in a peroxidase catalyzed reaction to form a blue dye.	Same
Specimen dilution	Not required	Same
Materials	Lipoprotein lipase, cholesterol esterase, cholesterol oxidase, peroxidase, and diarylimidazole leuco dye	Cholesterol esterase, cholesterol oxidase, peroxidase, and diarylimidazole leuco dye
Detector	Reflectance (615 nm)	Reflectance (660 nm)
Test time	Approx. 4 minute warm-up (on-board) plus 6 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	Abell Kendall	Not known
Sample Type	Pre-treated serum or plasma	Same
Specimen volume	10 µl test volume (85 ± 15 µl applied volume)	10 µl
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with each lot.	Run Vitros DT II calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	mg/dL or mmol/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE™ HDL-Cholesterol	Vitros HDLC DT Slides
Specimen pre-treatment	Required	Required
Reportable range	10 to 110 mg/dL	1 to 110 mg/dL
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ HDL-Cholesterol	Vitros HDLC DT Slides
Detection limit	10 mg/dL	1 mg/dL
Reportable range	10 to 110 mg/dL	1 to 110 mg/dL
Accuracy	Mean recovery 109%	Not provided
Precision	Total CV, 33 mg/dL, 6.5%	Total CV, 41 mg/dL, 3.2%
Method comparison	CARESIDE™ = 0.97 (Vitros HDLC DT) - 1.5 mg/dL, r = 0.97	
Linearity	Linearity by mixing and by dilution yielded slope and correlation coefficient within acceptable limits.	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid, 1 mg/dL Bilirubin, 10 mg/dL Hemoglobin, 250 mg/dL Protein 5 - 9 g/dL Triglycerides 1500 mg/dL	Ascorbic Acid interferes (non-interfering concentration undefined)

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE™ HDL-Cholesterol product is as safe, effective, and performs as well as or better than the legally marketed predicate device



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 14 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth B. Asarch, Ph.D.
. VP Quality Systems and Regulatory Affairs
Exigent Diagnostics Inc.
6100 Bristol Parkway
Culver City, California 90230

Re: K981899
CARESIDE™ HDL-Cholesterol
Regulatory Class: I
Product Code: LBS
Dated: May 29, 1998
Received: June 1, 1998

Dear Dr. Asarch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

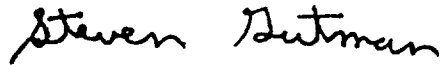
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE

510(k) Number:

Device Name: CARESIDE™ HDL-Cholesterol

Indications for use: For *in vitro* diagnostic use with Exigent Diagnostics' CARESIDE™ Analyzer to measure HDL-cholesterol from pre-treated serum or plasma specimens to aid in the diagnosis and treatment of patients with disorders of lipid and lipoprotein metabolism.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981899

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)